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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Paul James Davis

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER

FERNANDEZ, SUSAN EMILY

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

10/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/557,998	Applicant(s) DAVIS ET AL.	
	Examiner SUSAN E. FERNANDEZ	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-31 is/are pending in the application.
- 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-27 and 29-31 is/are rejected.
- 7) ☒ Claim(s) 2,4-27 and 29-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/10/09, 7/27/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 2, 2009, has been entered.

Claims 1, 2, and 4-31 are pending. Claim 28 is withdrawn.

Claims 1, 2, 4-27, and 29-31 are examined on the merits.

Claim Objections

Claims 2, 4-27, and 29-31 are objected to because of the following informalities: They each begin with "A" which should be replaced with "The". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-27, and 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The recitation of "an unused skin dressing" in claim 1 is considered new matter. The applicant points to paragraphs [0028]-[0030] and [0055] of the US-PGPUB document as support, but it is unclear how they provide support for the recitation that the skin dressing as described in the claims is "unused." The specification does not specify "unused," nor is there an explicit definition of the term. In the third paragraph on page 5 of the specification, it is recited that "The dressing components are kept separate before use, e.g. by being sealed in separate sterile, water-impervious packages such as laminated aluminum foil pouches." Does the applicant intend this recitation as the definition of the term "unused skin dressing"? Because the specification as filed fails to provide clear support for the new claim language, a new matter rejection is clearly proper. Claims 1, 2, 4-27, and 29-31 are thus rejected under 35 U.S.C. 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is indefinite since it requires that the first and second dressing components include polymers that are functionally similar to each other in terms of hydration. However, it is unclear how the two components can be similar in hydration since the first dressing component requires the enzyme in dried condition (thus providing a dry environment) while the second dressing component carries a source of water. It seems that their levels of hydration should be different. Thus, claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph.

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Claim 21 is indefinite because it is unclear what are the metes and bounds of the claim in terms of the monomers encompassed by the claim. It is unclear what monomers are encompassed which are "similar to monomers from which a polymeric support of the second dressing component is formed."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6, 7, 12, 22, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Powell (US 4,327,731) in light of Malloy et al. (US 4,581,336) and Amotz (US 4,665,028).

Powell discloses a system for indicating the presence of moisture in items including surgical dressings incorporating the moisture indicating system (column 1, lines 5-9). Figures 1 and 2 demonstrate embodiments of the invention and claim 3 describes an absorbent surgical dressing. Figure 1 shows an absorbent carrying medium 11 which supports a substrate 14 such as glucose, and an enzyme catalyst 12 (column 4, lines 10-23). When the substrate is glucose, the oxidoreductase glucose oxidase may be the enzyme in the system (claim 7). Each of these elements are impregnated into different layers of absorbent paper (column 4, lines 24-29). Impregnating a layer with enzyme results in a layer carrying immobilized enzyme. It is recognized in the prior art that this is the case. See Malloy et al. which teaches that "...glucose

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oxidase was immobilized thereon by impregnating the treated support with a solution containing...glucose oxidase” (column 20, lines 3-6). Also, see Amotz which teaches the step of impregnating a carrier with an enzyme solution to immobilize the enzyme (column 3, lines 66-68).

Powell indicates that “when moisture is present and reaches the substrate material, it releases some of the substrate material into the adjacent enzyme and chromogen system, and visible color is produced” (column 3, lines 10-13). Clearly, when moisture seeps into only the absorbent carrying medium 11 and the substrate 14 layers, or only the absorbent carrying medium 11 of the moisture indicating system, layers 11 and 14 or layer 11 alone is considered a "second dressing component carrying a source of water" while the enzyme catalyst 12 is considered a “first dressing component carrying oxidoreductase enzyme in dried condition.” Moreover, as the layers are absorbent and since the glucose in such a system becomes dissolved for reaction with the enzyme (column 3, lines 10-18), water indeed can migrate from the second component towards the first component and act to hydrate enzyme carried by the first component.

The limitation that the skin dressing is “unused” is a recitation of intended use. The intended use does not result in a structural difference between the claimed invention and the prior art. Thus, instant claim 1 is anticipated, as are claims 2-4, 6, 7, and 12.

Note further that the underside of the absorbent carrying medium 11 may include an adhesive (column 5, lines 25-31), thus meeting the limitation recited in instant claim 26. Moreover, given that the absorbent layers are present in the Powell composition that may be successively more absorbent toward the outside and draw moisture away from the wearer, the

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absorbent layers are of material that can be considered "hydration enhancers," thus meeting the limitation recited in instant claim 22.

A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-27, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powell, Malloy et al., and Amotz in view of Green (WO 01/28600, listed on 11/22/05 IDS), Munro et al. (US 2002/0037270) and Fuchs (US 5,483,697).

As discussed above, Powell, Malloy et al., and Amotz anticipate claims 1, 2, 4, 6, 7, 12, 22, and 26. However, Powell does not disclose that its absorbent surgical dressing includes a

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supply of iodide ions. Furthermore, Powell does not expressly disclose that the material used as the absorbent carrying medium or to carry the enzyme catalyst and substrate is hydrogel material.

Green discloses a multilayered wound dressing that comprises iodide wherein the layers can comprise lyophilized hydrogel (page 6, lines 20-25). In combination with an oxidoreductase and a substrate, the Green wound dressing can generate anti-infective iodine from the iodide present (page 9, lines 2-7). It is noted that the upper and lower layers of the Green bilayer dressing may be fabricated of the same polymer base (page 25, lines 1-14). Moreover, the material used meets the concentration requirements recited in instant claims 11 and 29 (page 19, lines 19-21).

Munro et al. discloses wound dressings comprising hydrogel compositions having bioadhesive properties (page 1, paragraph [0001]). In the dressing, interpenetrating polymer networks (IPN) are used in the hydrogel and may include water soluble polymers such as poly(2-acrylamido-2-methylpropane-sulphonic acid) or one of its salts and its copolymers (page 4, paragraph [0054]). Munro et al. notes that "...polymerising and crosslinking water soluble monomers in the presence of water soluble polymers, water and polyhydric alcohols produces hydrogel materials with enhance rheological and consequently adhesive properties" (page 4, paragraph [0053]).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have substituted the absorbent paper used in the surgical dressing with hydrogels which encompass those described in Green for wound dressings or hydrogel compositions described in Munro et al. for wound dressings (comprising poly(2-acrylamido-2-

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methylpropane-sulphonic acid) or salts thereof). One of ordinary skill in the art would have been motivated to do this because it would have been obvious to substitute one known wound dressing material for another to achieve the predictable result of treating wounds. The skilled artisan would have been motivated to use water soluble polymers such as poly(2-acrylamido-2-methylpropane-sulphonic acid) or its salts since they are known components of hydrogels for wound dressings and because it would have enhanced the rheological and adhesive properties of the dressing. It is noted that hydrogel material is shown by Green to be suitable for carrying oxidoreductases. Additionally, it would have been obvious to the person of ordinary skill in the art to have included iodide in the Powell dressing since, in combination with glucose oxidase and glucose reaction system, since it would have resulted in the production of anti-infective iodine when applied to wound. Thus, instant claims 5, 8-11, 13, 14, 18-21, 29, and 30 (obvious to vary concentration of the hydrogel by routine experimentation) are rendered obvious.

Furthermore, the selection of specific concentration of poly(2-acrylamido-2-methylpropane-sulphonic acid) or its salts and water in the hydrated hydrogel would have been a matter of routine optimization and experimentation on the part of the skilled artisan. Thus, instant claims 15-17 and 24 are rendered obvious.

The references also differ from the claimed invention in that they do not expressly disclose the presence in the wound dressing of a hydration enhancer or a moisturizer material.

Fuchs discloses that “The addition of humectants such as sorbitol, glycerol, sugar, corn syrup and other polyhydroxy compounds may help to retain moisture in the hydrogels” (column 9, lines 30-32).

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At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have included the humectants such as those listed in Fuchs in the hydrogel wound dressing rendered obvious by Powell, Green, and Munro et al. One of ordinary skill in the art would have been motivated to do this since it would have permitted retention of moisture, thus assisting in the reaction of the oxidoreductase with the substrate. Note that sorbitol and glycerol are among the compounds listed in instant claim 23 as "hydration enhancers," and amongst the compounds listed in the first paragraph on page 15 of the disclosure as "moisturiser materials." Thus, claims 23, 25, and 31 are rendered obvious.

Additionally, the references differ from the claimed invention in that they do not expressly disclose that the first and second components are separately sealed in respective packages prior to use. However, it would have been obvious to have kept the components separate in order to minimize bacterial contamination and prevent the reaction from taking place prior to treating a wound. Thus, claim 27 is rendered obvious.

A holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed July 2, 2009, have been fully considered but they are not persuasive. The applicant argues that since Powell teaches that the enzymes are "impregnated" in the carrier material, the enzymes are reversibly hydrated in the carrier and thus are not immobilized. However, the applicant has not provided evidence to show that impregnation actually results in the enzymes being reversibly hydrated in the carrier, or that reversible hydration indicates that the enzymes are not immobilized. It is unclear that the state of reversible

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hydration rules out that there is enzyme immobilization. As pointed out in MPEP 2145, Section I, "The arguments of counsel cannot take the place of evidence in the record." Furthermore, Malloy et al. and Amotz show that it is recognized in the art that impregnation of a material with enzyme results in immobilized enzyme. Even if the Powell invention was interpreted to not comprise "immobilized oxidoreductase enzyme," Green teaches enzyme immobilization (pages 23-24) and thus would have rendered it obvious when substituting the carrier material of the Powell invention with the hydrogel material of Green. It seems that applicant argues that one would not have been motivated to combine Green with Powell for the teaching of enzyme immobilization since the dressing structure of Green is dry, includes no enzyme substrate, and has as its objective the production of anti-infective iodine rather than the oxygen transport of the applicant's claimed invention. However, the instant claims indeed require the enzyme in dried condition. Moreover, Green would be used to modify the Powell invention with respect to the material on which the enzyme and substrate is entrapped (resulting in immobilized enzyme) and the inclusion of iodide ions. Though Green teaches the production of anti-infective iodine, the instant claims do not require that the objective of the claimed invention is oxygen transport or that iodine production should not occur.

Finally, the applicant argues that Powell does not teach a dressing initially supplied with water. However, the recitation of the dressing being "unused" is of the intended use of the invention. As pointed out above, the intended use does not result in a structural difference between the claimed invention and the prior art. Moreover, the specification does not provide a definition of the term "unused," and thus can encompass many different definitions. Therefore, Powell still anticipates the claimed invention.

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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
Examiner
Art Unit 1651

sef